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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,766	07/06/2001	Goran Forsberg	P02188US0 (10104199)	7699

7590

01/14/2003

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/14/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/900,766

Applicant(s)
Forsberg et al

Examiner
Patricia A. Duffy

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 18, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The Group and/or Art Unit of U.S. Patent application USSN 09/900,766 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Art Unit 1645.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-9 drawn to a conjugate of a bacterial superantigen with amino acid substitutions in region A and an antibody, classified in class 424, subclass 183.1.
 - II. Claims 10-14 drawn to a conjugate of a bacterial superantigen with amino acid substitutions in region B and an antibody, classified in class 424, subclass 183.1.
 - III. Claims 15-34 and 53-72 drawn to a conjugate of a bacterial superantigen with amino acid substitutions in region C and an antibody, classified in class 424, subclass 183.1.

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- IV. Claims 35-39 drawn to a conjugate of a bacterial superantigen with amino acid substitutions in region D and an antibody, classified in class 424, subclass 183.1.
- V. Claims 40-52 drawn to a conjugate of a bacterial superantigen with amino acid substitutions in region E and an antibody, classified in class 424, subclass 183.1.
- VI. Claims 73-92 drawn to methods for treating cancer by administering a conjugate comprising a bacterial superantigen with amino acid substitutions in region C and an antibody, classified in class 424, subclass 183.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case superantigen-antibody conjugates of Invention III can be used in the materially different process of an immunoassay for detection of food contamination or as a diagnostic for toxic shock syndrome and related conditions.

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4. The products of Inventions I-V have different structures and different immunological properties.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention I:

- (I) Superantigen: A- staphylococcal enterotoxin (SEE),
 B- *Streptococcus pyogenes* exotoxin (SPE),
 C- *Staphylococcus aureus* toxin (TSST-1),
 D- streptococcal mitogenic exotoxin (SME). and
 E- streptococcal superantigen (SSA),

if Species SEE is selected then Applicants are further required to select a specific substitution from each of (I) a position A substitution: 20, 21, 24, 27, 173 or 204; and (ii) a specific position C substitution: 79, 81, 83, or 84,

Invention II:

- (I) Superantigen: A- staphylococcal enterotoxin (SEE),

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B- *Streptococcus pyogenes* exotoxin (SPE),

C- *Staphylococcus aureus* toxin (TSST-1),

D- streptococcal mitogenic exotoxin (SME). and

E- streptococcal superantigen (SSA),

if Species SEE is selected then Applicants are further required to select a specific substitution from a position B substitution: 34, 35, 39, 40, 41, 42, 44, 45 or 49.

Invention III or VI:

Applicants are required to elect a single species combination of (I), (ii), (iii) and (iv) as set forth below.

(I) Superantigen: A- staphylococcal enterotoxin (SEE),

B- *Streptococcus pyogenes* exotoxin (SPE),

C- *Staphylococcus aureus* toxin (TSST-1),

D- streptococcal mitogenic exotoxin (SME), or

E- streptococcal superantigen (SSA),

(ii) Fab fragment: A -C215 or

B-5T4.

(iii) Cancer: A- lung,

B- breast,

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C-colon,

D- kidney,

E- pancreatic,

F- ovarian,

G- stomach,

H- cervix or

I- prostate.

(iv) Cytokine: A- IL-2,

B- IL-4,

C-IL-12,

D- GM-CSF,

E- tumor necrosis factors or

F- interferons.

Further if Species SEE is selected above, then Applicants are further required to *select a specific substitution from each of* (I) a position C substitution: 74, 75, 78, 79, 81, 83, or 84; and (ii) a specific position A substitution: 20, 21, 24, 27, 173, or 204.

Invention IV:

(I) Superantigen: A- staphylococcal enterotoxin (SEE),

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B- *Streptococcus pyogenes* exotoxin (SPE),

C- *Staphylococcus aureus* toxin (TSST-1),

D- streptococcal mitogenic exotoxin (SME). and

E- streptococcal superantigen (SSA),

if Species SEA is selected then Applicants are further required to select a specific substitution from (I) a position D substitution: 187, 188, 189 or 190.

Invention V:

(I) Superantigen: A- staphylococcal enterotoxin (SEE),

B- *Streptococcus pyogenes* exotoxin (SPE),

C- *Staphylococcus aureus* toxin (TSST-1),

D- streptococcal mitogenic exotoxin (SME). and

E- streptococcal superantigen (SSA),

if Species SEA is selected then Applicants are further required to *select a specific substitution from each of* (I) a position E substitution: 217, 220, 222, 223, 225 or 227; (ii) a specific position A substitution: 20, 21, 24, 27, 173 or 204; (iii) a specific region B substitution: 34, 35, 39, 40, 41, 42, 44, 45 or 49; (iv) a specific region C substitution: 74, 75, 78, 79, 81, 83, or 84; and (v) a specific region D substitution: 187, 188, 189 or 190.

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7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the independent claims 1, 10, 15, 40, and 53 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added

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after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

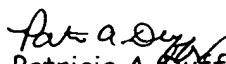
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
January 9, 2003


Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600